4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0971] (formerly Docket FDA-2008-N-0041) (formerly 2008N-0004)

Guidance for Industry on Acute Bacterial Otitis Media: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Acute Bacterial Otitis Media: Developing Drugs for Treatment." This guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for the treatment of acute bacterial otitis media (ABOM). This guidance finalizes the revised draft guidance of the same name issued on January 18, 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Acute Bacterial Otitis Media: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the overall clinical development of drugs to support an indication for the treatment of ABOM, defined in the guidance as "the recent or acute onset of inflammation of the middle ear caused by a bacterial pathogen." This guidance finalizes the revised draft guidance issued on January 18, 2008, which in turn revised the draft guidance for industry entitled "Acute Otitis Media — Developing Antimicrobial Drugs for Treatment" issued in 1998. Changes from the revised draft guidance are incorporated in the appropriate sections of the guidance and are based on comments received to the docket for the draft guidance. In addition, developments in

scientific and medical information and technology in the treatment of ABOM are included in this guidance. This guidance fulfills the statutory requirement described in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the guidance within 5 years.[1] This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act of 2012 that FDA review guidances for the conduct of clinical trials with respect to antibacterial and antifungal drugs and revise such guidances as appropriate.[2]

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment of ABOM. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under 0910-0014 and 0910-0001, respectively. The collections of information referred to in the guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under 0910-0581.

[1] See Title IX, section 911, of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).
[2] See Title VIII, section 804(a)(1), of the Food and Drug Administration Safety and Innovation Act of 2012 (Public Law 112-144).

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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